TABLE OF CONTENTS OF APPENDIX

PAGE

Judgment of the United States Court of Appeals for the Federal Circuit for which review is sought, dated May 17, 2000 ..... App. 1

Order of the United States District Court for the Eastern District of North Carolina, dated March 10, 1999 ..... App. 3

Order of the United States Court of Appeals for the Federal Circuit denying rehearing, dated July 11, 2000 ..... App. 18

[Filed May 17, 2000]

NOTE: Pursuant to Fed. Cir. R. 47.6, this deposition is not citable as precedent. It is a public record. The disposition will appear in tables published periodically.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

99-1362, - 1363, -1364

TORPHARM, INC.,

Plaintiff-Appellant,

v.

GENPHARM INC. and MYLAN LABORATORIES, INC.,

Defendants-Appellees,

and

NOVOPHARM, LTD., NOVOPHARM USA, INC., and GRANUTEC, INC.,

Defendants-Appellees.

JUDGMENT

ON APPEAL from the United States District Court for the Eastern District of North Carolina in CASE NO(S). 97-CV-658, 97-CV-686, and 97-CV-968.

This CAUSE having been heard and considered it is ORDERED AND ADJUDGED:

AFFIRMED. *See* Fed. Cir. R. 36

PER CURIAM RADER, GAJARSA, and LINN, *Circuit Judges*,

ENTERED BY ORDER OF THE COURT

/s/ Jan Horbaly
Jan Horbaly, Clerk

DATED May 17 2000

App. 3

[Filed March 10, 1999]

IN THE
UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

No. 5:97-CV-686-BO(3)
No. 5:97-CV-658-BO(2)
No. 5:97-CV-968-BO(3)

GENPHARM INC., and MYLAN LABORATORIES, INC., Plaintiffs, v. TORPHARM, INC. Defendant.	ORDER (under seal)
TORPHARM, INC., Defendant/Counter-Plaintiff, v. GENPHARM, INC., Plaintiff/Counter-Defendant, and MYLAN LABORATORIES, INC., Counter-Defendant.	
NOVOPHARM LIMITED, and NOVOPHARM USA, INC., Plaintiffs, v. TORPHARM, INC., Defendant.	

TORPHARM, INC.,	)	
Plaintiff,	)	SEALED
v.	)	
NOVOPHARM, LTD.,	)	
NOVOPHARM USA, INC., and	)	
GRANUTEC, INC.,	)	
Defendants.	)	
	)	

These cases are before the Court on various motions, including dispositive motions. This order will address one nondispositive motion that is necessary to make the dispositive motions ripe for ruling, and will grant certain dispositive motions. As a result, those remaining motions not specifically addressed will be moot.

BACKGROUND

These cases involve Form 1 ranitidine hydrochloride. Form 1 ranitidine hydrochloride was disclosed in several patents belonging to Glaxo Wellcome Inc., which were issued in the late 1970s and early 1980s. Ranitidine hydrochloride gained wide use in the treatment of ulcers. On April 7, 1995, an application was filed for what would become United States Patent No. 5,523,423 ("the '423 Patent"). TorPharm is the assignee and present owner of the '423 patent. Claim 1 of the '423 patent describes a form of Form 1 ranitidine hydrochloride having (i) a bulk density of not less than about 0.23 grams/milliliter and (ii) a tap density of not less than about 0.28 grams/milliliter, along with "improved filtration and drying characteristics." The parties stipulate that Claims 2-8 of the '423 patent are no longer at issue.

A. *Novopharm, Ltd. and Novopharm USA v. TorPharm (5:97-CV-658-BO(2))*

TorPharm v. Novopharm, Ltd., Novopharm USA, and Granutec, Inc. (5:97-C V-968-BO(3))

On August 21, 1997, Novopharm and Novopharm USA filed a complaint against TorPharm seeking declaratory judgment of non-infringement and invalidity of the '423 patent. TorPharm counterclaimed, alleging infringement of the '423 patent. This action is Civil Action No. 5-97-CV-658-BO(2).

On December 18, 1997, TorPharm filed a complaint in the Northern District of Illinois against Novopharm, Novopharm USA, and Granutec, Inc., alleging willful infringement of the '423 patent. That action was transferred to the Eastern District of North Carolina, and is Civil Action No. 5:97-968-BO(3). Novopharm, Novopharm USA, and Granutec[1] counterclaimed, seeking declaratory judgment of patent invalidity and non-infringement.

These two actions were consolidated for purposes of discovery and trial. Novopharm has filed a number of dispositive motions. On June 11, 1998, Novopharm filed for Summary Judgment alleging that the '423 patent is invalid under 35 U.S.C. § 102(b), also known as the "on-sale" bar. Novopharm has also moved for summary judgment on the grounds that the '423 patent is invalid for failure to comply with the "definiteness" and "enablement" requirements of 35 U.S.C. § 112. There is a

---

[1] For purposes of convenience, this order will abbreviate the parties Novopharm, Ltd., Novopharm USA, Inc. and Granutec, Inc. as "Novopharm."

pending motion to increase the page limit for Novopharm's Memorandum in Reply to TorPharm's Opposition to Novopharm's Motion for Summary Judgment Under Fed. R. Civ. P. 56(c). For good cause shown, this Motion will be granted, and the underlying Motion for Summary Judgment is ripe for ruling, as is Novopharm's second motion seeking summary judgment.

B. Genpharm v. TorPharm; Genpharm and Mylan[2] v. TorPharm (5:97-CV-686-BO(3))

On August 28, 1997, Genpharm filed a Complaint in this Court seeking a declaratory judgment of non-infringement and invalidity of United States Patent No. 5,523,423 ("the '423 patent"). Genpharm seeks a judgment declaring the '423 patent invalid, an injunction permanently enjoining TorPharm and its agents from enforcing the '423 patent against Genpharm, costs, and certain other relief.

TorPharm counterclaimed, alleging infringement of the '423 patent by Genpharm and its distributor, Mylan. TorPharm seeks an injunction enjoining Genpharm and Mylan from infringing the '423 patent, damages, and certain other relief.

Genpharm and Mylan put forward various affirmative defenses to TorPharm's counterclaim. These include an allegation that the '423 patent is invalid for failure to satisfy the conditions for patentability set forth in 35

---

[2] For reasons of convenience, the parties Genpharm Inc. and Mylan Laboratories, Inc. will be referred to in this order as "Genpharm" or "Genpharm and Mylan."

U.S.C. §§ 102-03 and/or failure to comply with the requirements of 35 U.S.C. §§ 112 and 116.

On August 21, 1998, Genpharm and Mylan filed for Summary Judgment on the grounds that TorPharm's '423 Patent is invalid due to the on-sale bar. This Motion essentially adopts the position laid out in Novopharm's Motion for Summary Judgment described above. Genpharm has also moved for summary judgment on the grounds that the '423 patent is invalid for obviousness. Genpharm also makes the alternative argument that TorPharm's '423 patent, if valid, does not encompass the product that Genpharm is importing into the United States, and thus Genpharm is not in infringement of the '423 patent. All of these motions are ripe for ruling.

C. Consolidation of the Cases

On March 3, 1998, the Court held a hearing in these matters. These matters were earlier consolidated for purposes of discovery, and at the March 3 hearing, the parties acknowledged that the issues at hand in the matters are identical. Therefore, the Court will address TorPharm's disputes with both Genpharm and Novopharm at this time.

ANALYSIS

A motion for summary judgment cannot be granted unless there are no genuine issues of material fact for trial. Fed. R. Civ. P. 56(c); *See Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). The movant must demonstrate the lack of a genuine issue of fact for trial, and if that

burden is met, the party opposing the motion must "go beyond the pleadings" and come forward with evidence of a genuine factual dispute. *Id.* at 324 (1986). The Court must view the facts and the inferences drawn from the facts in the light most favorable to the non-moving party. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986). Conclusory allegations are not sufficient to defeat a motion for summary judgment. *Cf. Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

A. The "On Sale" Bar of 35 U.S.C. § 102(b)

The subject matter of the '423 patent is a form of Form 1 ranitidine hydrochloride having (i) a bulk density of not less than about 0.23 grams/milliliter and (ii) a tap density of not less than about 0.28 grams/milliliter. Novopharm and Genpharm, in separate summary judgment motions, argue that the claims of the '423 patent are invalid under 35 U.S.C. § 102(b) because the subject matter of those claims was "on sale" in the United States more than one year before April 7, 1995, the date upon which TorPharm filed its application for the '423 patent.[3]

According to records produced to the Court, in mid-1992 Interchem Corporation ("Interchem"), a United States supplier of pharmaceutical bulk raw materials,

---

[3] According to 35 U.S.C. § 102, "A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. . ."

sold over 600 pounds[4] of bulk Form 1 ranitidine hydrochloride to Geneva Pharmaceuticals, Inc. ("Geneva"). This large quantity of bulk Form 1 ranitidine hydrochloride ("Form 1") was composed of three lots of Form 1. Two of these three lots of Form 1 had bulk densities of more than .23 grams/milliliter and tap densities of more than .28 grams/milliliter.[5] Therefore, more than three years before TorPharm applied for the '423 patent, a quantity of material with the characteristics described in the '423 patent was "on-sale" in the United States.

The question of whether a particular activity or transaction raises the on-sale bar under § 102(b) is a question of law. *See Robotic Vision Systems v. View Engineering, Inc.*, 112 F.3d 1163, 1167 (Fed. Cir. 1997). The Supreme Court has recently addressed the standards for application of the on-sale bar. *See Pfaff v. Wells Elecs., Inc.*, 119 S.Ct. 304 (Nov. 10, 1998). "[T]he on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. . . . Second, the invention must be ready for patenting." *Id.* at 311-12.

---

[4] According to the evidence before the Court, Interchem sold Geneva 289.800 kilograms of Form 1 ranitidine hydrocholoride at a price of $530.00/kilogram, for a total cost of $153,594.00.

[5] After taking delivery of the three lots of Form 1 from Interchem, Geneva ran a standard battery of tests on the lots. These tests demonstrated that two of the three lots had bulk densities of more than 0.23 grams/milliliter and tap densities of more than 0.28 grams/milliliter. Geneva Pharmaceuticals, Inc. Master Analytical Form Raw Material Product Specifications and Data Sheets, dated September 1992.

In this case, it is clear that there was not only a commercial offer for sale, but that the offer was accepted, and an actual sale took place. Record evidence of a signed purchase agreement before the critical date establishes an offer for sale sufficient to invoke the on-sale bar. *See Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1333 (Fed. Cir. Dec. 7, 1998). It is also clear that the invention was ready for patenting,[6] as it had been reduced to practice. Indeed, a quantity of the material in question was delivered to purchaser Geneva.

TorPharm argues that the material purchased by Geneva may not have had the "improved drying and filtration characteristics" claimed in the '423 patent. However, the '423 patent does not describe these "improved drying and filtration characteristics," and also does not describe how to measure them.[7] The only way

---

[6] This, of course, assumes that the subject matter of the '423 patent was appropriate for patenting at all. As discussed below, the '423 patent should never have been issued. However, that discussion is irrelevant to an analysis of whether the on-sale bar applies.

[7] As discussed below, it would be impossible to show that a quantity of Form 1 had the "improved filtration and drying characteristics" claimed in the '423 patent, because no quantifiable description of these claimed characteristics is found in the patent. The applicants for the '423 patent merely stated that "the products of the prior art are smaller, more fluffy and therefore have inferior drying and filtration characteristics to Applicant's invention." Therefore, it appears that any quantitation of these "improved filtration and drying characteristics" must be directly related to the bulk and tap density measurements described in the '423 patent. Neither the Courts nor the public should be expected to apply the amorphous and subjective limitation of "improved filtration and drying characteristics" to the '423 patent beyond those bulk and tap density measurements.

to distinguish the product claim in the '423 patent from any other Form 1 ranitidine hydrochloride is by the bulk and tap densities provided. Two of the three lots purchased by Geneva met these tests.[8]

TorPharm also argues that the evidence which proves the sale to Geneva is not admissible, and that summary judgment should not be based on this allegedly inadmissible evidence. However, the records in question are admissible under the business records hearsay exception of Federal Rule of Evidence 803(6).[9] The "Geneva Pharmaceuticals, Inc. Master Analytical Form Raw Material Product Specification and Data Sheets" relied upon by Genpharm and Novopharm fall squarely within the definition of business records. The various records in question have been appropriately authenticated, as required by Federal Rule of Evidence 901, by the deposition testimony of Geneva managing agent Sandra Tigner, who identified all necessary records, including the purchase order by which Geneva ordered the Form I at issue, the invoice sent to Geneva by Interchem, the check paying for the Form 1 at issue, and the raw

---

[8] TorPharm also claims that the material purchased by Geneva was somehow contaminated. However, they provide no evidence to this effect. Unsubstantiated allegations or statements such as that made by TorPharm are not sufficient to defeat a motion for summary judgment.

[9] Under Rule 803(6), "[a] memorandum, report, record, or data compilation, in any form, of acts, events, conditions, opinions, or diagnoses, made at or near the time by or from information transmitted by, a person with knowledge, if kept in the course of a regularly conducted business activity. . ." is not excluded by the hearsay rule.

material data sheets used to record the bulk and tap densities of the Form 1 sold to Geneva.

Finally, TorPharm argues that the sale of Form 1 to Geneva was secret and confidential, and thus did not trigger the on-sale bar. However, there is absolutely no requirement that a sale be publicized to trigger 35 U.S.C. § 102(b). *See J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 884 (1986). Indeed, for purposes of the § 102(b) bar, Geneva was a member of the relevant public. *See id.* at 1583. In the well-known Corset Case, the Supreme Court stated that "[i]f an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used, such use is public, even though the use and knowledge of the use may be confined to one person." *Egbert v. Lippman*, 104 U.S. 333, 336 (1881). Thus, the sale of Form 1 material from Interchem to Geneva, even if "secret," was sufficient to trigger the on-sale bar.

Genpharm and Novopharm have produced ample admissible evidence to support their assertion that claim 1 of the '423 patent is invalid under the on-sale bar of 35 U.S.C. § 102(b). Therefore, their motions for summary judgment will be granted.

B. Other Grounds for Summary Judgment

Because the Court is granting the motions for summary judgment based on the on-sale bar, the other summary judgment motions need not be addressed. However, in the interests of completeness, the Court

will briefly analyze certain issues raised by other dispositive motions filed in this matter.

Genpharm alleges that the '423 patent is invalid on grounds of obviousness. While a detailed analysis of the factors laid out in *Graham v. John Deere* is beyond the scope of this order, a brief application of the *Graham* factors to this case demonstrates that the '423 patent indeed is invalid on grounds of obviousness. The four *Graham* factors are (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the prior art and the claimed invention; and (4) secondary differences such as commercial success, long felt but unresolved needs, and failure of others. 383 U.S. 1, 17 (1966).

The undisputed evidence in these cases shows that the'423 patent claims involve at most a routine optimization of known factors to produce material with the same or similar bulk and tap densities as the prior art. Routine optimization such as this should not lead to issuance of a patent. *See In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996); *see also Merck & Co., Inc. v. Biocraft Labs. Inc.*, 874 F.2d 804, 809 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 975 (1989).

Analysis of the evidence shows that the principles necessary to production of the material claimed in the '423 patent were in the public domain by 1993 at the latest. In fact, much of the necessary information was published in this Court's opinion in *Glaxo, Inc. v. Novopharm Ltd.*, 830 F. Supp. 871 (E.D.N.C. 1993), *aff'd* 52 F.3d 1043 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 988 (1995). This information was therefore prior art well be-

fore issuance of the '423 patent for purposes of the first *Graham* obviousness factor.[10]

The other *Graham* factors do not support TorPharm's position. The evidence shows that the tap and bulk densities claimed in the '423 patent are not significantly different from prior art material. The process claims in the '423 patent call for use of a C3-C4 alcohol solvent under anhydrous conditions. However, Glaxo's prior art long ago disclosed the use of a C4 alcohol solvent. Thus, the second *Graham* factor mitigates against validity of the '423 patent. Undisputed deposition testimony demonstrated that ordinary skill in the art is a chemist with a Ph.D. or a B.S. and some experience."[11] Further undisputed testimony showed that producing material with the properties claimed in the '423 patent would be routine skill to such a chemist. Therefore, the third *Graham* factor does not support TorPharm's position. TorPharm has not presented significant arguments relating to the fourth *Graham* factor.

---

[10] TorPharm argues that a legal order such as this Court's opinion in *Novopharm I* is not prior art generally available to one of ordinary skill in the art. Considering the pervasive litigation surrounding drug patents, the Court finds that a published legal opinion would certainly be brought to the attention of every significant pharmaceutical company by its counsel. What the companies do with that information once they receive it is irrelevant; the information is available to the companies' employees and agents, who presumably are of ordinary skill in the art.

[11] TorPharm argues that one deponent's opinion that reasonable skill in the art is akin to a "reasonable pharmaceutical formulator" contradicts other experts' opinion that a chemist with a Ph.D. or a B.S. and experience is the level of ordinary skill in the art. The Court finds these statements to be completely compatible.

After full consideration of the evidence, it is clear to the Court that detailed application of the *Graham* factors would show that the '423 patent is invalid for obviousness. If the Court were not granting summary judgment based on the on-sale bar, it would grant summary judgment based on obviousness.

Novopharm argues that the '423 patent is invalid for failure to comply with the "definiteness" and "enablement" requirements of 35 U.S.C. § 112. Because the Court is granting summary judgment based on the on-sale bar, it will give only cursory attention to this position.

Upon examination of the evidence, it appears to the Court that the specific bulk and tap density limitations laid out in Claim 1 of the '423 patent are the only things that differentiate or define the "improved form of Form 1 ranitidine hydrochloride" claimed in the patent. Because the '423 patent does not describe the specific experimental method to be used to measure the bulk and tap densities of the claimed Form 1 material, it is difficult for others to replicate the claimed material based on the description in the patent. It is argued that the experimental error in measuring the bulk density of Form 1 ranitidine hydrochloride by any one method is between 10 and 20%. Therefore, it is unlikely that others can replicate the product claimed in the '423 patent without knowing which method or combination of methods was used.[12] This may conflict with the

---

[12] TorPharm claims that the word "about" in Claim 1 cures any lack of definiteness in the description of the appropriate methodology for measuring bulk and tap density. While it may

(continued...)

"definiteness" requirement of 35 U.S.C. § 112, which considers "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Morton Int'l. Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993). Because Claim 1's failure to provide specific methods requires others to conduct "undue experimentation" to duplicate the claimed material, the '423 patent may not meet the "enablement" standard of 35 U.S.C. § 112. *See Genentech Inc. v. Nova Nordisk A/V*, 108 F.3d 1361, 1365 (Fed. Cir. 1997), *cert. denied*, 118 S.Ct. 397 (1997).[13]

Because the Court has already presented ample justification for its decision to grant summary judgment against TorPharm, it need not and will not reach a conclusion on the issues of "definiteness" and "enablement." Because this Court finds that the '423 patent is invalid, it need not address Genpharm's alternative argument that summary judgment should be granted because Genpharm has not infringed the '423 patent.

---

[12] (...continued)
be entirely acceptable to use such a modifier to describe an acceptable variance, the possibility of a 20% variation would not appear to be covered by the word "about."

[13] TorPharm argues that those of ordinary skill in the art would have no difficulty replicating the work described in the '423 patent. While this defense might serve to protect TorPharm from summary judgment on definiteness or enablement grounds, it would appear to weaken its case on the issue of obviousness.

CONCLUSION

After full consideration of the parties' arguments, and for the reasons discussed above, the Motion for Summary Judgment Under Rule 56(c) filed by Novopharm Ltd., Novopharm USA, and Granutec, Inc on June 11, 1998 is GRANTED. The Motion for Summary Judgment of Patent Invalidity under 35 U.S.C. § 102(b) filed by Genpharm Inc. and Mylan Laboratories, Inc. on August 21, 1998 is also GRANTED. Accordingly, this Court rules that United States Patent No. 5,523,423 is invalid for the reasons described above. Because the summary judgment motions filed by Genpharm and Novopharm have been granted as described above, all other motions in this case are now moot, and are accordingly DISMISSED AS MOOT. The clerk shall provide copies of this order to the parties and their counsel.

SO ORDERED.

This 8th day of March, 1999.

/s/ Terrence W. Boyle
TERRENCE W. BOYLE
Chief United States District Judge

I certify the foregoing to be a true
and Correct copy of the original.
David W. Daniel, Clerk
United States District Court
Eastern District of North Carolina

By _____
Deputy Clerk

[Filed July 11, 2000]

United States Court of Appeals
for the Federal Circuit

99-1362, -1363, -1364

TORPHARM, INC.,

Plaintiff-Appellant,

v.

GENPHARM INC. and
MYLAN LABORATORIES, INC.,

Defendants-Appellees,

and

NOVOPHARM, LTD., NOVOPHARM USA, INC.,
and GRANUTEC, INC.,

Defendants-Appellees.

ORDER

A combined petition for panel rehearing and rehearing en banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEES and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service.

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on July 18, 2000.

Circuit Judge LOURIE and Circuit Judge SCHALL did not participate in the vote.

FOR THE COURT,

/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: July 11, 2000

cc: Hugh L. Moore
Robert F. Green, Edgar H. Haug

TORPHARM V NOVOPHARM, 99-1362, -1363, -1364
(DCT - 97-CV-658)

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.